

## § 524.463

## 21 CFR Ch. I (4–1–12 Edition)

### § 524.463 Copper naphthenate.

(a) *Amount.* The drug is a 37.5 percent solution of copper naphthenate.

(b) *Sponsors.* See Nos. 000856, 017135, and 058829 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Apply daily to affected hooves until fully healed.

(2) *Indications for use.* As an aid in treating horses and ponies for thrush caused by organisms susceptible to copper naphthenate.

(3) *Limitations.* Use on horses and ponies only. Avoid contact around eyes. Do not contaminate feed. Do not use in horses intended for human consumption.

[47 FR 4250, Jan. 29, 1982, as amended at 68 FR 55825, Sept. 29, 2003; 71 FR 38074, July 5, 2006]

### § 524.575 Cyclosporine ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 2 milligrams of cyclosporine.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply a 1/4-inch strip of ointment to the affected eye(s) every 12 hours.

(2) *Indications for use.* For management of chronic keratoconjunctivitis sicca (KCS) and chronic superficial keratitis (CSK) in dogs.

(3) *Limitations.* Place ointment directly on cornea or into the conjunctival sac. Safety of use in puppies, pregnant or breeding animals has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 48651, Sept. 20, 1995, as amended at 62 FR 48940, Sept. 18, 1997]

### § 524.590 Diclofenac.

(a) *Specifications.* Each gram of cream contains 10 milligrams diclofenac sodium.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Apply a 5-inch (5") ribbon of cream twice daily over the affected joint for up to 10 days and rub thoroughly into the hair covering the joint until it disappears.

(2) *Indications for use in horses.* For the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock and pastern) joints.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 40767, July 7, 2004, as amended at 74 FR 26782, June 4, 2009; 74 FR 47436, Sept. 16, 2009]

### § 524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.

#### § 524.660a Dimethyl sulfoxide solution.

(a) *Specifications.* Dimethyl sulfoxide contains 90 percent of dimethyl sulfoxide and 10 percent of water.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used or intended for use as a topical application to reduce acute swelling due to trauma:

(i) In horses administered 2 or 3 times daily in an amount not to exceed 100 milliliters per day. Total duration of therapy should not exceed 30 days.

(ii) In dogs administered 3 or 4 times daily in an amount not to exceed 20 milliliters per day. Total duration of therapy should not exceed 14 days.

(2) Not for use in horses and dogs intended for breeding purposes nor in horses slaughtered for food. Other topical medications should only be used when the dimethyl sulfoxide treated area is thoroughly dry. Do not administer by any other route.

(3) For use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996]

#### § 524.660b Dimethyl sulfoxide gel.

(a) *Specifications.* Dimethyl sulfoxide gel, veterinary contains 90 percent dimethyl sulfoxide in an aqueous gel.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For use on horses and dogs as a topical application to reduce acute swelling due to trauma.